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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0135; FRL-10008-20]

Ethalfluralin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation decreases the tolerance for residues of ethalfluralin in or on potato. Gowan Company requested this tolerance modification under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2019-0135, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket

available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any

aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2019-0135 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2019-0135, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/where-send-comments-epa-dockets*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of May 9, 2019 (84 FR 20320) (FRL-9992-36), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8F8721) by Gowan Company, P.O. Box 5569, Yuma, AZ 85366. The petition requested that the tolerance in 40 CFR 180.416 for residues of the herbicide ethalfluralin in or on potato be reduced from 0.05 parts per million (ppm) to 0.01 ppm. That document referenced a summary of the petition prepared by Gowan Company, the registrant, which is available in the docket, *http://www.regulations.gov*. No relevant comments were received on the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to

make a determination on aggregate exposure for ethalfluralin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with ethalfluralin follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Ethalfluralin has low acute toxicity by the oral, dermal, and inhalation routes of exposure. It is moderately irritating to the eye and produces moderate to severe skin irritation. It is a dermal sensitizer.

The hazard database for ethalfluralin indicates that the liver is the primary target organ in rats and mice, with hematological effects also observed in rats and dogs. No systemic toxicity up to the limit dose was seen in the 21-day dermal toxicity study in rabbits. There were no signs of immunotoxicity or neurotoxicity in the database.

No reproductive or developmental effects were observed in rats, and although there were developmental effects (sternal variations, incomplete cranial development and resorptions) in rabbits, these were seen in the presence of maternal toxicity.

Ethalfluralin has been classified as a possible human carcinogen (Group C) based on positive genotoxicity assays (two positive Salmonella assays and a positive assay for chromosomal aberrations) and the findings from a two-year chronic carcinogenicity study in rats (showing an increased incidence of mammary gland fibroadenomas and combined adenomas/fibroadenomas in female rats).

Specific information on the studies received and the nature of the adverse effects caused by ethalfluralin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document *Ethalfluralin. Human Health Risk Assessment for the Section 3 Registration on Potato* in docket ID number EPA-HQ-OPP-2019-0135.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides*.

A summary of the toxicological endpoints for ethalfluralin used for human risk assessment is shown in Table 1 of this unit.

Table 1. Summary of Toxicological Doses and Endpoints for Ethalfluralin for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13-50 years of age)	NOAEL = 75 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.75 mg/kg/day aPAD = 0.75 mg/kg/day	Rabbit Developmental Toxicity Study MRID: 00129057, 00250596 Developmental LOAEL = 150 mg/kg/day based on increased number of resorptions and increased sternal and cranial variations
Acute dietary (General population including infants and children)	A single dose effect relevant to the general US population including infants and children was not identified in the toxicity studies conducted with ethalfluralin.		
Chronic dietary (All populations)	NOAEL= 4 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.04 mg/kg/day cPAD = 0.04 mg/kg/day	Dog Chronic Oral Toxicity Study MRID: 00153371, 92062014 LOAEL = 20 mg/kg/day based on increased urinary bilirubin, variations in erythrocyte morphology, increased thrombocyte count, and increased erythroid series of the bone marrow.
Cancer (Oral, dermal, inhalation)	Ethalfluralin has been classified as a possible human carcinogen (Group C) based on increased mammary gland fibro-adenomas & combined adenomas/fibro-adenomas in female rats. $Q_1^* = 8.9 \times 10^{-2}$ $(mg/kg/day)^{-1}$		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. mg/kg/day = milligram/kilogram/day. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to ethalfluralin, EPA considered exposure under the petitioned-for tolerance as well as all existing ethalfluralin tolerances in 40 CFR 180.416. EPA assessed dietary exposures from ethalfluralin in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are

performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for ethalfluralin. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA used tolerance-level residues and assumed 100 percent crop treated (PCT) for all commodities.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003-2008 NHANES/WWEIA. As to residue levels in food, EPA used tolerance-level residues and assumed 100 PCT for all commodities.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that ethalfluralin should be classified as a "Possible human carcinogen (Group C)" and a linear approach has been used to quantify cancer risk.

A refined ethalfluralin chronic cancer dietary (food and drinking water) analysis was conducted using half the field trial limit of detection (LOD) value for all potato commodities, monitoring data generated by USDA's Pesticide Data Program (PDP) for most commodities (soybean grain; soy infant formula; canned black, kidney, pinto, and garbanzo beans; cantaloupe; watermelon; cucumber; summer squash; winter squash; and peanut butter), average PCT data for some commodities, and tolerance-level residues and 100 PCT for remaining commodities.

iv. *Anticipated residues and percent crop treated (PCT) information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA

section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

• Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.

• Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.

• Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for existing uses as follows:

Canola/rapeseed (2.5%); cantaloupe (5%); cucumber (55%); peanut (15%); pumpkin (20%); squash (20%); sunflower (5%); and watermelon (15%). The remaining commodities assumed 100% CT.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for

the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the Agency would use less than 1% or less than 2.5% as the average PCT value, respectively. The maximum PCT figure is the highest observed maximum value reported within the recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses less than 2.5% as the maximum PCT.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which ethalfluralin may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for ethalfluralin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of ethalfluralin. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the Surface Water Concentration Calculator (SWCC) and the Pesticide Root Zone Model for GroundWater (PRZM-GW) models, the estimated drinking water concentrations (EDWCs) of ethalfluralin for acute exposures are estimated to be 26.1 parts per billion (ppb) for surface water and <0.001 ppb for ground water. The EDWCs for chronic exposures are estimated to be 0.57 ppb for surface water and <0.001 ppb for ground water. The surface water EDWC for cancer exposure was estimated to be 0.36 ppb; the groundwater EDWC is the same as for acute and chronic exposures, <0.001 ppb.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 26.1 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 0.57 ppb was used to assess the contribution to drinking water. For cancer dietary risk assessment, the water concentration of value 0.36 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure*. The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Ethalfluralin is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found ethalfluralin to share a common mechanism of toxicity with any other substances, and ethalfluralin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that ethalfluralin does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. As summarized in Unit III.A., no reproductive or

developmental effects were observed in rats, and although there were developmental effects (sternal variations, incomplete cranial development and resorptions) in rabbits, these were seen in the presence of maternal toxicity. The resorptions are considered a maternal and developmental effect and the skeletal effects are minor, so these are not considered evidence of qualitative susceptibility.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for ethalfluralin is adequate to characterize potential prenatal and postnatal risk for infants and children.

ii. There is no indication that ethalfluralin is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that ethalfluralin results in increased susceptibility in *in utero* rats in the prenatal developmental study or in young rats in the 2-generation reproduction study. Although there were developmental effects (sternal variations, incomplete cranial development and resorptions) seen in the rabbit prenatal study, there is low concern for increased susceptibility, as these effects were seen in the presence of maternal toxicity. Additionally, the dose and endpoints chosen for risk assessment are protective of the developmental effects observed in the rabbit developmental toxicity studies.

iv. There are no residual uncertainties identified in the exposure databases. The acute and chronic dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. The refined cancer dietary exposure assessment was based on USDA PDP monitoring data, field trial data for potatoes, and average PCT estimates. EPA made conservative

(protective) assumptions in the ground and surface water modeling used to assess exposure to ethalfluralin in drinking water. These assessments will not underestimate the exposure and risks posed by ethalfluralin.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to ethalfluralin will occupy <1% of the aPAD for females 13 to 49 years old, the population group receiving the greatest exposure. There are no residential uses for ethalfluralin.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to ethalfluralin from food and water will utilize <1% of the cPAD for all population subgroups. There are no residential uses for ethalfluralin.

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because there are no residential uses, ethalfluralin is not expected to pose short- or intermediate-term risk.

4. *Aggregate cancer risk for U.S. population*. The cancer aggregate risk assessment

combines exposures to ethalfluralin in food and drinking water only. The most highly-exposed population subgroups in the dietary (food and drinking water) cancer assessment were adults 20 to 49 years old and females 13 to 49 years old with a cancer risk estimate of $\leq 8.8 \times 10^{-7}$. EPA generally considers cancer risks (expressed as the probability of an increased cancer case) in the range of 1 in 1 million (or 1×10^{-6}) or less to be negligible.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to ethalfluralin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology [gas chromatography (GC) with electron capture detection (ECD); Pesticide Analytical Manual (PAM, Vol. II, section 180.416 Methods I and II)] is available to enforce the tolerance expression. Method I and II are applicable for the analysis of ethalfluralin residues in/on plant and animal commodities, respectively.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however,

FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established an MRL for ethalfluralin on potato.

C. International Trade Considerations

In this Final Rule, EPA is reducing the existing tolerance for residues of ethalfluralin on potato from 0.05 ppm to 0.01 ppm. Available residue data demonstrate that tolerances at 0.01 ppm are sufficient to cover residues on potato.

In accordance with the World Trade Organization's (WTO) Sanitary and Phytosanitary Measures (SPS) Agreement, EPA intends to notify the WTO of this revision in order to satisfy its obligation. In addition, the SPS Agreement requires that Members provide a "reasonable interval" between the publication of a regulation subject to the Agreement and its entry into force to allow time for producers in exporting Member countries to adapt to the new requirement. At this time, EPA is establishing an expiration date for the existing tolerances to allow those tolerances to remain in effect for a period of six months after the effective date of this final rule, in order to address this requirement. After the six-month period expires, residues of ethalfluralin on potato cannot exceed the new tolerance of 0.01 ppm.

This reduction in tolerance levels is not discriminatory; the same food safety standard contained in the FFDCA applies equally to domestically produced and imported foods.

V. Conclusion

Therefore, the tolerance is decreased for residues of ethalfluralin in or on potato from 0.05 ppm to 0.01 ppm.

VI. Statutory and Executive Order Reviews

This action modifies an existing tolerance under FFDCA section 408(d) in response to a

petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among

the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 7, 2020.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.416, amend the table in paragraph (a) as follows:

i. Add an entry for "Potato" after "Pea, dry, seed" and before the current entry for "Potato"; and

ii. Revise the current entry for "Potato".

The addition and revision read as follows:

§ 180.416 Ethalfluralin; tolerances for residues

(a) * * *

Commodity	Parts per million
* * * * * * *	
Potato	0.01
Potato[1]	0.05
* * * * * * *	

[1] This tolerance expires on January 28, 2021.

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[FR Doc. 2020-16266 Filed: 7/27/2020 8:45 am; Publication Date: 7/28/2020]